

Exhibit 13

Archived: Friday, September 1, 2023 2:46:59 PM

From: [Rhoad, Robert](#)

To: '[Lessler, Jay](#)'

Cc: [Black, Martin Reilly, Luke](#)

Subject: RE: Mankind Pharma's Varenicline Tartrate Product, ANDA No. 214255

Importance: Normal

Sensitivity: None

Jay,

We wrote to you last Friday (August 25) with minor tweaks to the proposed non-disclosure agreement, and in light of Mankind's imminent launch of its generic varenicline tablets, asked you to confirm whether Mankind would commit to producing the relevant portions of its ANDA and the applicable DMF (i.e., documents sufficient to show how its generic varenicline tablets and the API contained in them are manufactured) by Monday, specifically noting that time was of the essence. Despite the urgency of this matter, we have not heard back from you.

If this were a more traditional Hatch-Waxman Act case, then Mankind would have had to give Par notice of any basis on which it contends that its tablets do not infringe Par's patents and ordinarily would have also provided Par with confidential access to the relevant portions of its ANDA, after which Par would have had an opportunity to evaluate a possible infringement claim and, if filed, have that claim resolved by the court *before* Mankind was able to launch its tablets and irreversibly disrupt the varenicline market. Although that statutory regime does not formally apply under the unique circumstances presented here, Par has sought Mankind's cooperation in providing, on an expedited basis, the functional equivalent thereof, so as to avoid if possible the need to commence infringement proceedings unnecessarily. So far, those efforts have not borne fruit.

In light of Mankind's imminent launch, we need to bring those efforts to a close. Accordingly, Par requests that Mankind either (a) commit to producing copies of the requested materials on a confidential basis to us this week (i.e., by the close of business on Friday), or (b) agree not to launch its tablets until at least seven (7) days after it does produce those materials to us.

Please let us know by no later than Thursday if Mankind will comply with that request. If not, Par will have no choice but to file suit seeking to compel Mankind to produce those materials on an expedited basis and barring Mankind from launching its tablets until at least seven days thereafter. In any such lawsuit, unless and until Mankind produces those materials, it will bear the burden of proving non-infringement pursuant to 35 U.S.C. § 295. We hope and trust that that will not be necessary and are available to meet and confer with you should you wish to discuss the matter further.

Sincerely yours,

Bob

Robert D. Rhoad

Dechert LLP

A Pennsylvania Limited Liability Partnership

+1 609 955 3269 Direct

robert.rhoad@dechert.com

dechert.com



From: Rhoad, Robert
Sent: Friday, August 25, 2023 4:30 PM
To: Lessler, Jay <jay.lessler@blankrome.com>
Cc: Black, Martin <martin.black@dechert.com>; Reilly, Luke <luke.reilly@dechert.com>
Subject: RE: Mankind Pharma's Varenicline Tartrate Product, ANDA No. 214255

Jay,

Thank you for your email. Par has made a couple of tweaks to the NDA, and I attach clean and redlined versions of the proposed revised agreement.

Please note that the USPTO has allowed the claims of one of Par's pending applications – see the attached notice of allowance and copy of the allowed claims.

Please confirm whether Mankind will produce on Monday the sections of the Mankind ANDA and applicable DMF that describe the composition of its varenicline tablets and the methods used to manufacture them and the varenicline API contained in them, as we understand that the launch of Mankind's tablets is imminent such that time is of the essence. We would prefer to have access to those materials before any suit is filed, but if Mankind refuses to produce them sufficiently in advance of the launch to allow us to evaluate whether Mankind is infringing Par's patents, Par will have no choice but to file suit and seek to halt any launch until a determination as to infringement can be made.

Regards,

Bob

Robert D. Rhoad

Dechert LLP

A Pennsylvania Limited Liability Partnership
+1 609 955 3269 Direct
robert.rhoad@dechert.com
dechert.com



From: Lessler, Jay <jay.lessler@blankrome.com>
Sent: Thursday, August 24, 2023 5:14 PM
To: Rhoad, Robert <robert.rhoad@dechert.com>

Cc: Black, Martin <martin.black@dechert.com>; Reilly, Luke <luke.reilly@dechert.com>

Subject: RE: Mankind Pharma's Varenicline Tartrate Product, ANDA No. 214255

[EXTERNAL EMAIL]

Dear Bob,

Attached are Mankind's proposed revisions to the NDA.

Regards,

Jay

Jay P. Lessler | BLANKROME

1271 Avenue of the Americas | New York, NY 10020

O: 212.885.5176 | F: 917.332.3773 | jay.lessler@blankrome.com

From: Rhoad, Robert <robert.rhoad@dechert.com>

Sent: Wednesday, August 23, 2023 2:39 PM

To: Lessler, Jay <jay.lessler@blankrome.com>

Cc: Black, Martin <martin.black@dechert.com>; Reilly, Luke <luke.reilly@dechert.com>

Subject: RE: Mankind Pharma's Varenicline Tartrate Product, ANDA No. 214255

You don't often get email from robert.rhoad@dechert.com. [Learn why this is important](#)

Dear Jay,

Please let us know the status of Mankind's review of the NDA and when we can expect to receive their response, as time is of the essence.

Regards,

Bob

Robert D. Rhoad

Dechert LLP

A Pennsylvania Limited Liability Partnership

+1 609 955 3269 Direct

robert.rhoad@dechert.com

dechert.com



From: Lessler, Jay <jay.lessler@blankrome.com>
Sent: Wednesday, August 16, 2023 8:34:01 PM
To: Black, Martin <martin.black@dechert.com>
Cc: Reilly, Luke <luke.reilly@dechert.com>
Subject: RE: Mankind Pharma's Varenicline Tartrate Product, ANDA No. 214255

[EXTERNAL EMAIL]

Dear Mr. Black,

Thank you for your August 15th letter.

We are reviewing the non-disclosure agreement provided with your August 11th letter and will provide our proposed revisions next week.

Regards,

Jay

Jay P. Lessler | BLANKROME
1271 Avenue of the Americas | New York, NY 10020
O: 212.885.5176 | F: 917.332.3773 | jay.lessler@blankrome.com

From: Black, Martin <martin.black@dechert.com>
Sent: Tuesday, August 15, 2023 2:34 PM
To: Lessler, Jay <jay.lessler@blankrome.com>
Cc: Reilly, Luke <luke.reilly@dechert.com>
Subject: Mankind Pharma's Varenicline Tartrate Product, ANDA No. 214255

You don't often get email from martin.black@dechert.com. [Learn why this is important](#)

Please see the attached correspondence.

Marty

This e-mail is from Dechert LLP, a law firm, and may contain information that is confidential or privileged. If you are not the intended recipient, do not read, copy or distribute the e-mail or any attachments. Instead, please notify the sender and delete the e-mail and any attachments. Thank you.

This message and any attachments may contain confidential or privileged information and are only for the use of the intended recipient of this message. If you are not the intended recipient, please notify the Blank Rome LLP or Blank Rome Government Relations LLC sender by return email, and delete or destroy this and all copies of this message and all attachments. Any unauthorized disclosure, use, distribution, or reproduction of this message or any attachments is prohibited and may be unlawful.

This e-mail is from Dechert LLP, a law firm, and may contain information that is confidential or privileged. If you are not the intended recipient, do not read, copy or distribute the e-mail or any attachments. Instead, please notify the sender and delete the e-mail and any attachments. Thank you.